

## **REMARKS**

As amended, claims 1-3 and 5 are pending. Claims 4 and 6-13 have been canceled without disclaimer or prejudice to their filing in future continuation or divisional applications. Claims 1-3 and 5 have been amended to modify claim dependencies or to more particularly point out and distinctly claim the invention. Support for the amendments may be found through the specification and the claims as originally filed, including on page 7, lines 17-19 and on page 12, lines 14-18. No new matter has been added as a result of the claim amendments.

Also, merely for the sake of clarifying the record, the applicant notes that in view of the claims addressed in the Restriction Requirement mailed September 29, 2009, the Preliminary Amendment filed with the application on May 9, 2006 was not entered by the Office. It is further noted that claims sought to be canceled in the Preliminary Amendment have been canceled with the claim amendments herein, and that modifications to claim dependencies have also been made herein.

### **1. Claim Objections**

Claims 4 and 5 are objected to as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. The applicant has canceled claim 4 and amended claim 5, thus obviating the objection.

### **2. Claim Rejections under 35 U.S.C. 112, second paragraph**

Claims 8-9 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. While the applicant traverses, claims 8-9 have nevertheless been canceled herein and, therefore, this rejection is obviated.

### **3. Claim Rejections under 35 U.S.C. 112, first paragraph**

Claims 1-5, 8 and 9 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. As an initial matter, claims 4, 8 and 9 have been canceled, thus obviating their rejection.

As to the remaining claims, the Action asserts the invention is not enabled because the range of cancer type to be detected is too broad. While the applicant traverses, claims 1-3 and 5

have nevertheless been amended to recite the detection of the presence or the risk of *breast* cancer. Support for the amendment can be found for example in original claim 4.

The Action further asserts that it is unlikely that a test based on an individual gene would be able to provide sufficient accuracy for early detection. Additionally, the Action asserts that the neither the specification nor the art confirm DD20 as a risk factor for cancer, and also that the increased DD20 expression levels shown in the differential display experiments used in the examples of the present application could be due to a number of factors and as such this does not serve as evidence that DD20 is a risk factor for cancer. The applicant traverses these assertions.

Nevertheless, without conceding to the merits of these assertions, the applicant has amended claim 1 to specify that in addition to detecting the presence or expression of the gene identified as SEQ ID No. 1, detection of one or more known biomarkers of breast cancer is also required. Support for the amendment may be found on page 7, lines 17-19 and on page 12, lines 14-18. The applicant respectfully contends that the claims as amended are fully enabled as the detection of DD20 expression in combination with known biomarkers of breast cancer increases the specificity of such methods (in addition to allowing further characterization of breast tumors).

More specifically, the invention as presently claimed does not involve the identification of a single biomarker, such as DD20, but rather involves detecting the presence of a known biomarker plus a further biomarker (DD20). Moreover, it is also noted at the final paragraph of page 12 of the application that DD20 compares favorably with some of the most highly regarded "standard" breast cancer markers, such as ER $\alpha$  and c-ErbB-2, as evident in the expression distribution of both sets of markers in sample breast tissue. In other words, the methods of the present invention accurately diagnose the presence or risk of breast cancer on the basis of at least one known biomarker but, in addition, utilization of DD20 enables the method to more accurately diagnose the presence or risk of breast cancer, and may provide further information on the type of breast cancer and the stage of the disease. The effectiveness of DD20 in aiding in the diagnosis of the presence or risk of breast cancer would be clear to one of skill in the art in view of the specification and the demonstrated similar expression patterns of DD20 to known breast cancer biomarkers.

Thus, the applicant respectfully contends that the invention as presently claimed is fully enabled to one of skill in the art and requests reconsideration and withdrawal of the rejection under 35 USC § 112, first paragraph.

### **CONCLUSION**

Applicants respectfully contend that in view of the claim amendments and remarks contained herein, the application is in condition for allowance. If the Examiner believes that prosecution of the instant application would be facilitated by a conversation, the Examiner is encouraged to contact the undersigned as indicated below.

Respectfully submitted,

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